AMY W. SCHULMAN
DLA PIPER LLP
1251 Avenue of the Americas
New York, NY 10020
Telephone: (212) 335-4500
Facsimile: (212) 335-4501
amy.schulman@dlapiper.com

STUART M. GORDON (SBN: 037477)
GORDON & REES LLP
Embarcadero Center West
275 Battery Street, Suite 2000
San Francisco, CA 94111
Telephone: (415) 986-5900
Facsimile: (415) 986-8054
sgordon@gordonrees.com

MICHAEL C. ZELLERS (SBN: 146904)
TUCKER ELLIS & WEST LLP
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Facsimile: (213) 430-3409
michael.zellers@tuckerellis.com

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION, AND
G.D. SEARLE LLC

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

IN RE CELEBREX AND BEXTRA MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION *This document relates to* VIVIAN D. COBB, Plaintiff, vs. PFIZER, INC., PHARMACIA CORPORATION, G.D. SEARLE L.L.C., and MONSANTO COMPANY, Defendants.	MDL Docket No. 1699 CASE NO. 3:08-cv-00257-CRB **PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE, LLC'S ANSWER TO COMPLAINT** **JURY DEMAND ENDORSED HEREIN**

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company[1]) ("Pharmacia") and G.D. Searle LLC ("Searle") and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.

PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Celebrex® (celocoxib) ("Celebrex®"). Accordingly, this Answer can only be drafted generally. Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Celebrex®.

II.

ORIGINAL ANSWER

Response to Allegations Regarding Parties

1. Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

2. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age or state of residence and, therefore, deny the same.

3. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of

[1] Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed Celebrex®. Given that Plaintiff alleges in the Complaint that Monsanto Company was involved in distributing Celebrex®, *see* PLAINTIFF'S COMPLAINT at ¶ 7, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

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San Francisco, CA 94111

Minnesota. Defendants state that the remaining allegations in this paragraph of the Complaint assert legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pfizer is a Delaware corporation with its principal place of business in New York. Defendants admit that Pfizer is registered to do business in the State of Minnesota. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pfizer and Pharmacia co-promoted and marketed Celebrex® in the United States, including Minnesota, to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that, during certain periods of time, Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law

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authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever manufactured, marketed, sold, or distributed Celebrex®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed Celebrex®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by reference into Defendants' responses to each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

8. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants deny the remaining allegations in this paragraph of the Complaint.

9. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who

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are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

10. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

11. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Minnesota. Defendants are without knowledge sufficient to form a belief as to the allegations in this paragraph of the Complaint regarding the amount in controversy, and, therefore, deny the same. However, Defendants admit that Plaintiff claims the amount in controversy satisfies the jurisdictional amount of this Court. Defendants deny the remaining allegations in this paragraph of the Complaint.

Response to Factual Allegations

13. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are

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adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Celebrex® caused Plaintiff injury or damages and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

16. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants state that the allegations in this paragraph of the Complaint regarding aspirin, naproxen, and ibuprofen are not directed toward Defendants, and, therefore, no response

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is required. Defendants admit that Celebrex® is in a class of drugs that are, at times, referred to as being a non-steroidal anti-inflammatory ("NSAID") drugs. Defendants deny the remaining allegations in this paragraph of the Complaint.

18. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

19. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

20. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent that a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

21. Defendants state that the allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Plaintiff fails to provide the proper context for the remaining allegations in this paragraph and Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of the allegations and, therefore, deny the remaining allegations in this paragraph of the Complaint.

22. Defendants state that the allegations in this paragraph of the Complaint regarding

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San Francisco, CA 94111

"predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information sufficient to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants state that, as stated in the FDA-approved labeling for Celebrex®, "[t]he mechanism of action of Celebrex is believed to be due to inhibition of prostaglandin synthesis, primarily via inhibition of cyclooxygenase-2 (COX-2), and at therapeutic concentrations in humans, Celebrex does not inhibit the cyclooxygenase-1 (COX-1) isoenzyme." Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants admit that Searle submitted a New Drug Application ("NDA") for Celebrex® on June 29, 1998. Defendants admit that, on December 31, 1998, the FDA granted approval of Celebrex® for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; and (2) for relief of the signs and symptoms of rheumatoid arthritis in adults. Defendants admit that, on December 23, 1999, the FDA granted approval of Celebrex® to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") as an adjunct to usual care (e.g., endoscopic surveillance surgery). Defendants deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that Celebrex® was launched in February 1999. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that

the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

25. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

26. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

27. Defendants state that the referenced FDA Update speaks for itself and respectfully refer the Court to the FDA Update for its actual language and text. Any attempt to characterize the FDA Update is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

28. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

29. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

30. Defendants admit that a supplemental NDA for Celebrex® was submitted to the FDA on June 12, 2000. Defendants assert that the submission speaks for itself and any attempt to characterize it is denied. Defendants admit that a Medical Officer Review dated September 20,

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275 Battery Street, Suite 2000
San Francisco, CA 94111

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275 Battery Street, Suite 2000
San Francisco, CA 94111

2000, was completed by the FDA. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

31. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

33. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants state that the transcripts of the FDA Arthritis Drugs Advisory Committee hearings speak for themselves and respectfully refer the Court to the transcripts for their actual language and text. Any attempt to characterize the transcripts is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

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275 Battery Street, Suite 2000
San Francisco, CA 94111

36. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that the referenced articles speak for themselves and respectfully refer the Court to the articles for their actual language and text. Any attempt to characterize the articles is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Plaintiff fails to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

41. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

42. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Plaintiff fails to provide the proper context for the allegations concerning "Public Citizen" in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

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Defendants deny the remaining allegations in this paragraph of the Complaint.

43. Defendants admit that there was a clinical trial called APC. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Plaintiff fails to provide the proper context for the allegations concerning "Data Safety Monitoring Board" in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. Defendants state that the referenced Alert for Healthcare Professionals speaks for itself and respectfully refer the Court to the Alert for Healthcare Professionals for its actual language and text. Any attempt to characterize the Alert for Healthcare Professionals is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

48. Defendants admit that there was a clinical trial called PreSAP. Plaintiff fails to provide the proper context for the allegations concerning "other Celebrex trials" contained in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. As for the allegations in this paragraph of the Complaint regarding the PreSAP study, Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual

language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Plaintiff fails to provide the proper context for the allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced studies speak for themselves and respectfully refer the Court to the studies for their actual language and text. Any attempt to characterize the studies is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

51. Defendants state that the referenced Medical Officer Review speaks for itself and respectfully refer the Court to the Medical Officer Review for its actual language and text. Any attempt to characterize the Medical Officer Review is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

52. Defendants state that allegations regarding Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiff fails to provide the proper context for the allegations regarding Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiff fails to provide the proper context for the allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such

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275 Battery Street, Suite 2000
San Francisco, CA 94111

allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

54. Defendants state that allegations regarding Merck and Vioxx® in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Plaintiff fails to provide the proper context for the allegations regarding Merck and Vioxx® in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

56. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

57. Defendants state that allegations in this paragraph of the Complaint are not directed toward Defendants, and therefore no response is required. To the extent that a response is deemed required, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

58. Defendants deny the allegations in this paragraph of the Complaint.

59. Defendants state that Celebrex® was and is safe and effective when used in accordance

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with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations contained in this paragraph of the Complaint.

60. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

61. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

62. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

63. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants admit that the FDA Division of Drug Marketing, Advertising, and Communications ("DDMAC") sent letters to Searle dated October 6, 1999, April 6, 2000, and November 14, 2000. Defendants state that the referenced letters speak for themselves and respectfully refer the Court to the letters for their actual language and text. Any attempt to

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San Francisco, CA 94111

characterize the letters is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

65. Defendants admit that the DDMAC sent a letter to Pharmacia dated February 1, 2001. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

66. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

67. Defendants admit that the DDMAC sent a letter to Pfizer dated January 10, 2005. Defendants state that the referenced letter speaks for itself and respectfully refer the Court to the letter for its actual language and text. Any attempt to characterize the letter is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

69. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information,

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which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

72. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

75. Defendants deny the allegations in this paragraph of the Complaint.

76. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

79. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

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275 Battery Street, Suite 2000
San Francisco, CA 94111

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

80. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® are and were adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence

84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's

Complaint as if fully set forth herein.

85. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but denies having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

87. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable

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275 Battery Street, Suite 2000
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275 Battery Street, Suite 2000
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standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

88. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

89. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's medical condition or whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the

remaining allegations in this paragraph of the Complaint.

92. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Answering the unnumbered paragraph following Paragraph 92 of the Complaint, Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Liability

93. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

94. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

95. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

96. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

97. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

98. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

99. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, and deny the remaining allegations in this paragraph of the Complaint.

100. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® is defective, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

104. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

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state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint

105. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

106. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

107. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Breach of Express Warranty

108. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

109. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

110. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

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applicable standards of care and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

111. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

112. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

113. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

114. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

115. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

116. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or

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damages, and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Implied Warranty

118. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

119. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

120. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

121. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

122. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-

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275 Battery Street, Suite 2000
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approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

123. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® is a prescription medication which is approved by the FDA for the following indications: (1) for relief of the signs and symptoms of osteoarthritis; (2) for relief of the signs and symptoms of rheumatoid arthritis in adults; (3) for the management of acute pain in adults; (4) for the treatment of primary dysmenorrhea; (5) to reduce the number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) as an adjunct to usual care (e.g., endoscopic surveillance surgery); (6) for relief of signs and symptoms of ankylosing spondylitis; and (7) for relief of the signs and symptoms of juvenile rheumatoid arthritis in patients two years of age and older. Defendants deny the remaining allegations in this paragraph of the Complaint.

124. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit to providing FDA-approved prescribing information for Celebrex®. Defendants deny the remaining allegations in this paragraph of the Complaint.

125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that, in the ordinary case, Celebrex® was expected to reach users and consumers without substantial change from the time

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of sale. Defendants deny the remaining allegations in this paragraph of the Complaint.

126. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

127. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

128. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

129. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Fraudulent Misrepresentation and Concealment

130. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

131. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

132. Defendants state that Celebrex® was and is safe and effective when used in accordance

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with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

133. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

134. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

135. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

136. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

137. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

138. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

139. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the

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remaining allegations in this paragraph of the Complaint.

140. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

141. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

142. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

143. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

144. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Unjust Enrichment

145. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

146. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Celebrex® in the United States to be prescribed by healthcare providers who

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are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Celebrex® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Celebrex® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

147. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

148. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

149. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Celebrex®, and, therefore, deny the same. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Celebrex® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

151. Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer For Relief

Answering the unnumbered paragraph of the Complaint headed "Prayer for Relief," Defendants deny any wrongful conduct, deny that Celebrex® caused Plaintiff injury or damages, and deny the remaining allegations this paragraph of the Complaint, including all subparts.

III.

GENERAL DENIAL

Defendants deny all allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.

AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Celebrex® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Celebrex® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Third Defense

3. At all relevant times, Defendants provided proper warnings, information and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Celebrex® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is pleaded in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same were caused by the negligence or fault of the Plaintiff and Plaintiff's damages, if any, are barred or reduced by the doctrines of comparative fault and contributory negligence and by the failure to mitigate damages.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff was not caused by Celebrex®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Celebrex® is a prescription medical product, available only on the order of a licensed physician. Celebrex® provided an adequate warning to Plaintiff's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Celebrex® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Celebrex® at the time of the occurrence of the injuries alleged by Plaintiff was legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Celebrex® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the

Complaint, the same were caused by the unforeseeable alteration, change, improper handling, abnormal use, or other unforeseeable misuse of Celebrex® by persons other than Defendants or persons acting on its behalf after the product left the control of Defendants.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Celebrex®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Celebrex®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Celebrex® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and the Constitutions of the States of Minnesota, Ohio, and California, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

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275 Battery Street, Suite 2000
San Francisco, CA 94111

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and, therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause

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275 Battery Street, Suite 2000
San Francisco, CA 94111

of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and the Constitutions of the States of Minnesota, Ohio, and California. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Celebrex®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Celebrex® was designed,

tested, manufactured and labeled in accordance with the state-of-the-art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the

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275 Battery Street, Suite 2000
San Francisco, CA 94111

applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Celebrex® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Celebrex® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Celebrex® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to

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275 Battery Street, Suite 2000
San Francisco, CA 94111

implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Celebrex®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by Federal Rule of Civil Procedure 9(b) and should be dismissed.

Fifty-fifth Defense

55. Defendants state on information and belief that the Complaint and each purported cause of action contained therein is barred by the statutes of limitations contained in California Code of Civil Procedure §§ 335.1 and 338 and former § 340(3), such other statutes of limitation as may apply.

Fifty-sixth Defense

56. Defendants state on information and belief that any injuries, losses, or damages suffered by Plaintiff was proximately caused, in whole or in part, by the negligence or other actionable conduct of persons or entities other than Defendants. Therefore, Plaintiff's recovery against Defendants, if any, should be reduced pursuant to California Civil Code § 1431.2.

Fifty-seventh Defense

57. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious under California Civil Code § 3294, and, therefore, any award of punitive damages is barred. Any claim for punitive damages is also barred under California Civil Code § 3294(b).

Fifty-eighth Defense

58. Plaintiff's claim for punitive damages is barred pursuant to Minn. Stat. § 549.191.

Fifty-ninth Defense

59. Plaintiff's claims for punitive damages are barred, in whole or in part, by § 2315.21 of

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275 Battery Street, Suite 2000
San Francisco, CA 94111

the Ohio Revised Code and are subject to all provisions of the Ohio Revised Code.

Sixtieth Defense

60. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources and the provisions of the Ohio Revised Code.

Sixty-first Defense

61. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Ohio law.

Sixty-second Defense

62. Plaintiff's damages, if any, must be reduced by the percentage of fault attributable to Plaintiff and to nonparties as provided by the Ohio Revised Code.

Sixty-third Defense

63. One or more of Plaintiff's claims for damages are subject to statutory limits on certain types of damages, and the Court is without jurisdiction to enter judgment for Plaintiff beyond the limits set forth in the Ohio Revised Code.

Sixty-fourth Defense

64. Ohio Senate Bill 120 and Senate Bill 80, now codified in various sections throughout the Ohio Revised Code, bar or limit one or more of Plaintiff's claims, including the limits and restrictions on damages set forth herein.

Sixty-fifth Defense

65. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.

PRAYER

WHEREFORE, Defendants pray for judgment as follows:

1. That Plaintiff takes nothing from Defendants by reason of the Complaint;

2. That the Complaint be dismissed;

3. That Defendants be awarded their costs for this lawsuit;

4. That the trier of fact determine what percentage of the combined fault or other liability

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275 Battery Street, Suite 2000
San Francisco, CA 94111

of all persons whose fault or other liability proximately caused Plaintiff's alleged injuries, losses or damages is attributable to each person;

5. That any judgment for damages against Defendants in favor of Plaintiff be no greater than an amount which equals their proportionate share, if any, of the total fault or other liability which proximately caused Plaintiff's injuries and damages; and

6. That Defendants have such other and further relief as the Court deems appropriate.

May 30, 2008 GORDON & REES LLP

By: :_____/s/_____
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

May 30, 2008 TUCKER ELLIS & WEST LLP

By: :_____/s/_____
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111

JURY DEMAND

Defendants Pfizer Inc., Pharmacia Corporation, and G.D. Searle LLC, hereby demand a trial by jury of all the facts and issues in this case pursuant to 38(b) of the Federal Rules of Civil Procedure.

May 30, 2008

GORDON & REES LLP

By: :_____/s/_____
Stuart M. Gordon
sgordon@gordonrees.com
Embarcadero Center West
275 Battery Street, 20th Floor
San Francisco, CA 94111
Telephone: (415) 986-5900
Fax: (415) 986-8054

May 30, 2008

TUCKER ELLIS & WEST LLP

By: :_____/s/_____
Michael C. Zellers
michael.zellers@tuckerellis.com
515 South Flower Street, Suite 4200
Los Angeles, CA 90071-2223
Telephone: (213) 430-3400
Fax: (213) 430-3409

Attorneys for Defendants
PFIZER INC., PHARMACIA CORPORATION, AND G.D. SEARLE LLC

Gordon & Rees, LLP
275 Battery Street, Suite 2000
San Francisco, CA 94111